Claims:

1. A method to predict which patient will be more likely to develop edema when treated with a drug comprising:

a) determining RNA expression levels in a biological sample for a plurality of the 13 predictor genes shown in Table 2;

b) comparing patients gene expression profile to the mean *No Edema* expression profiles shown in Table 3;

c) determining the similarity between the two gene expression profiles resulting from the comparison in (b);

d) determining the likelihood that the patient will develop edema when treated with a drug by means of the degree of similarity determined in (c).

2. The method of Claim 1, wherein the said similarity determined in (c) is the mathematical correlation coefficient obtained by comparing the said two gene expression profiles.

3. The method of Claim 2, wherein the said correlation coefficient determined in (c) is the Pearson Correlation Coefficient (PCC).

4. The method of Claim 3, wherein step (d) is determined by determining that the patient will be more likely to develop edema than not, when treated with a drug, if the PCC is <0.37; and determining that the patient will be more likely not to develop edema than to develop it if the PCC is ≥0.37.

5. A method to predict, with high sensitivity, which patients will be more likely to develop edema when treated with a drug, such that no more than 15% of *Edema* cases will be misclassified as having *No Edema*, comprising:

a) determining RNA expression levels in a biological sample for a plurality of the 13 predictor genes shown in Table 2;

b) comparing patients gene expression profile to the mean *No Edema* expression profiles shown in Table 3;

c) determining the PCC between the two gene expression profiles resulting from the comparison in (b);

d) determining that the patient will be more likely to develop edema than not, when treated with a drug, if the PCC is negative and <0.78; and

e) determining that the patient will be more likely not to develop edema than to develop it if the negative PCC is ≥0.78.

6. The method of any one of Claims 1 to 5, wherein the biological sample comprises a blood sample.

7. The method of any one of Claims 1 to 6, wherein all the 13 predictor genes in Table 2 are used.

8. The method of any one of Claims 1 to 7, wherein the drug is a tyrosine kinase inhibitor (TKI) .

9. The method of Claim 8, wherein the TKI is Imatinib or GLEEVEC™/GLIVEC®.

10. A method to predict which female patient will be more likely to develop edema when treated with a drug, comprising:

a) determining for the two copies of the IL-1β gene, present in the patient, the identity of the nucleotide pairs at the polymorphic site at position -511 base pairs upstream (at position 1423 of sequence X04500) from the transcriptional start site; and

b) determining that the patient will be likely to develop edema if both nucleotide pairs at this site are GC and determining that the patient will not be likely to develop edema if at least one nucleotide pair at this site is AT.

11. The method of Claim 10, wherein the drug is a TKI.

12. The method of Claim 11, wherein the TKI is Imatinib or GLEEVEC™/GLIVEC®.

13. A method to predict which female patient will be more likely to develop edema when treated with a drug, comprising:

a) determining for the two copies of the IL-1β gene, present in the patient, the identity of the nucleotide pairs at the polymorphic site at position -31 base pairs upstream (at position 1903 of sequence X04500) from the transcriptional start site; and

b) determining that the patient will be likely to develop edema if both nucleotide pairs at this site are AT and determining that the patient will not be likely to develop edema if at least one nucleotide pair at this site is GC.

14. The method of claim 13, wherein the drug is a TKI.

15. The method of claim 14, wherein the TKI is Imatinib or GLEEVEC™/GLIVEC®.

16. A method to predict which female patient will be more likely to develop edema when treated with a drug, comprising:

a) determination of the level of transcription of the IL-1β gene in a biological sample; and

b) determining that the patient would be likely to develop edema when treated with a drug if the level is above a threshold level.

17. A method to predict which female patient will be more likely to develop edema when treated with a drug, comprising:

a) determination of the level of the protein expressed by the IL-1β gene in a biological sample; and

b) determining that the patient would be likely to develop edema when treated with a drug if the level is above a threshold level.

18. The method of Claim 16 or 17, wherein the drug is a TKI.

19. The method of Claim 18, wherein the TKI is Imatinib or GLEEVEC™/GLIVEC®.

20. A method to predict which patient will be more likely to develop edema when treated with a drug comprising:

a) determining the pattern of protein expression in a biological sample for two or more of the protein products of the 13 predictor genes shown in Table 2;

b) comparing the pattern of protein expression with the pattern expected for the *Edema* and the *No Edema* expression profile shown in Table 3;

c) determining that if the pattern is more similar to the *No Edema* pattern that the patient will not be likely to develop edema when treated with a drug; and

d) determining that if the pattern is more similar to the *Edema* pattern that the patient will be likely to develop edema when treated with a drug.

21. The method of Claim 20, wherein the protein expression of a plurality of the 13 predictor genes shown in Table 2 is determined.

22. The method of Claim 21, wherein the protein expression of all the 13 predictor genes shown in Table 2 is determined.

23. The method of any one of Claims 20 to 22, wherein the drug is a TKI.

24. The method of Claim 23, wherein the TKI is Imatinib or GLEEVEC™/GLIVEC®.

25. A method to treat a patient with a drug comprising:

a) determining, by the use of the methods of any one of Claims 16 to 24, the likelihood that the particular patient will develop edema when exposed to the intended drug; and

b) modifying the intended drug therapy for that patient in a safe and appropriate manner based on the results of the determination in (a).

26. A method to design clinical trials for the testing of drugs comprising:

a) determining by the use of either the expression profiling or the genotyping methods described above the likelihood that a particular patient will develop edema when exposed to the test drug; and

b) assigning that patient to the appropriate classification in the clinical study based on the results of the determination in (a).

27. A method of treating a subject having, or at risk of having, edema comprising administering to the subject a therapeutically effective amount of an isolated nucleic acid molecule comprising an antisense nucleotide sequence derived from the IL-1β gene, which has the ability to change the transcription/translation of the IL-1β gene.

28. A method of treating a subject having, or at risk of having, edema comprising administering to the subject a therapeutically effective amount of an antagonist that inhibits/activates the protein encoded by the IL-1β gene.

29. The method of Claim 28, wherein the antagonist is an antibody specific for the protein.

30. The method of Claim 29, wherein the antibody is a monoclonal antibody.

31. The method of Claim 30, wherein the monoclonal antibody is conjugated to a toxic reagent.

32. A method of treating a subject having, or at risk of having, edema comprising administering to the subject a therapeutically effective amount of a nucleotide sequence encoding a ribozyme, which has the ability to decrease/increase the transcription/translation of the IL-1β gene.

33. A method of treating a subject having, or at risk of having, edema comprising administering to the subject a therapeutically effective amount of a double-stranded RNA

corresponding to the IL-1β gene, which has the ability to decrease the transcription/translation of the IL-1β gene.

34. A kit for predicting which patient will be more likely to develop edema when treated with a drug comprising a means for determining the pattern of protein expression corresponding to two or more of the 13 predictor genes shown in Table 2.

35. The kit of Claim 34, wherein the means is able to determine the pattern of protein expression corresponding to a plurality of the 13 predictor genes.

36. The kit of Claim 34 or 35, wherein the means is able to determine the pattern of protein expression corresponding to all the 13 predictor genes.

37. A kit for predicting which patient will be more likely to develop edema when treated with a drug comprising a means for determining the level of the protein expressed by the IL-1β gene.

38. The kit of any of Claims 34 to 37, wherein the means for determining the protein expression comprise antibodies, antibody derivatives, or antibody fragments.

39. The kit of any one of Claims 34 to 38, wherein the protein expression is determined through Western blotting utilizing a labeled antibody.

40. The kit of any one of Claims 34 to 39, further comprising means for obtaining a biological sample of the patient.

41. The kit of any one of Claims 34 to 40, further comprising a container suitable for containing the means for detecting the proteins and the biological sample of the patient.

42. The kit of any one of Claims 34 to 41, further comprising instructions for use and interpretation of the kit results.

43. A kit for predicting which patient will be more likely to develop edema when treated with a drug comprising:

(a) a means for determining the pattern of protein expression corresponding to the two or more of the 13 predictor genes shown in Table 2;

(b) a container suitable for containing the said means and the biological sample of the patient comprising the proteins, wherein the means can form complexes with the proteins;

(c) a means to detect the complexes of (b); and optionally

(d) instructions for use and interpretation of the kit results.

44. A kit for determining the protein expression pattern for the 13 predictor genes shown in Table 2 comprising:

a) a container comprising all the reagent necessary to determine the protein expression pattern; and

b) a label describing how to perform and interpret the analysis.

45. A kit for predicting which patient will be more likely to develop edema when treated with a drug comprising:

(a) a means for determining the level of the protein expressed by the IL-1β gene;

(b) a container suitable for containing the said means and the biological sample of the patient comprising the protein, wherein the means can form complexes with the protein;

(c) a means to detect the complexes of (b); and optionally

(d) instructions for use and interpretation of the kit results.

46. The method of any one of Claims 17 to 19, wherein the determination step (a) further comprises the use of a kit of any one of Claims 37 to 42, or 45.

47. The method of any one of Claims 20 to 24, wherein the determination step (a) further comprises the use of a kit of any one of Claims 34 to 36, or 38 to 44.

48. A kit for predicting which patient will be more likely to develop edema when treated with a drug comprising a means for determining the level of transcription of two or more of the 13 predictor genes shown in Table 2.

49. The kit of Claim 48, wherein the means is able to determine the level of transcription of a plurality of the 13 predictor genes.

50. The kit of Claim 48 or 49, wherein the means is able to determine the level of transcription of all the 13 predictor genes.

51. A kit for predicting which patient will be more likely to develop edema when treated with a drug comprising a means for determining the level of transcription of the IL-1β gene.

52. The kit of any one of Claims 48 to 51, wherein the means for determining the level of transcription comprise oligonucleotides or polynucleotides able to bind to the transcription products of said genes.

53. The kit of Claim 52, wherein the oligonucleotides or polynucleotides are able to bind mRNA or cDNA corresponding to said genes.

54. The kit of any one of Claims 48 to 53, wherein the level of transcription is determined by techniques selected from the group of Northern blot analysis, reverse transcriptase PCR, real-time PCR, RNAse protection, and microarray.

55. The kit of any one of Claims 48 to 54, further comprising means for obtaining a biological sample of the patient.

56. The kit of any one of Claims 48 to 55, further comprising a container suitable for containing the means for measuring the level of transcription and the biological sample of the patient.

57. The kit of any one of claims 48 to 56, further comprising instructions for use and interpretation of the kit results.

58. A kit for predicting which patient will be more likely to develop edema when treated with a drug comprising:

(a) a number of oligonucleotides or polynucleotides able to bind to the transcription products of the two or more of the 13 predictor genes shown in Table 2;

(b) a container suitable for containing the oligonucleotides or polynucleotides and the biological sample of the patient comprising the transcription products wherein the oligonucleotides or polynucleotide can bind to the transcription products;

(c) means to detect the binding of (b); and optionally

(d) instructions for use and interpretation of the kit results.

59. A kit for determining the expression pattern of the 13 predictor genes shown in Table 2 comprising:

a) a container comprising the necessary gene chip along with the needed reagents to develop it; and

b) instructions for the preparation, reading and interpretation of the resulting gene expression pattern.

60. A kit for predicting which patient will be more likely to develop edema when treated with a drug comprising:

(a) oligonucleotides or polynucleotides able to bind to the transcription products of the IL-1β gene;

(b) a container suitable for containing the oligonucleotides or polynucleotides and the biological sample of the patient comprising the transcription products wherein the oligonucleotides or polynucleotide can bind to the transcription products;

(c) means to detect the binding of (b); and optionally

(d) instructions for use and interpretation of the kit results.

61. The method of any one of Claims 1 to 9, wherein the determination step (a) further comprises the use a kit of any one of Claims 48 to 50, or 52 to 59.

62. The method of Claim 16, wherein the determination step (a) further comprises the use a kit of any one of Claims 51 to 57, or 60.

63. A kit for the identification of a polymorphism pattern at the IL-1β gene of a patient, said kit comprising a means for determining the genetic polymorphism pattern at the IL-1β gene at position 1423 of sequence X04500.

64. A kit for the identification of a polymorphism pattern at the IL-1β gene of a patient, said kit comprising a means for determining the genetic polymorphism pattern at the IL-1β gene at position 1903 of sequence X04500.

65. The kit of Claim 63 or 64, further comprising a means for obtaining a biological sample of the patient.

66. The kit of Claim 65, wherein the means comprises a DNA sample collecting means.

67. The kit of any one of Claims 63 to 66, wherein the means for determining a genetic polymorphism pattern at the specific polymorphic site comprises at least one gene specific genotyping oligonucleotide.

68. The kit of any one of Claims 63 to 67, wherein the means for determining a genetic polymorphism pattern at one of the specific polymorphic sites comprises two gene specific genotyping oligonucleotides.

69. The kit of any one of Claims 63 to 68, wherein the means for determining a genetic polymorphism pattern at one of the specific polymorphic sites comprises at least one gene specific genotyping primer composition comprising at least one gene specific genotyping oligonucleotide.

70. The kit of claim 69, wherein the gene specific genotyping primer composition comprises at least two sets of allele specific primer pairs.

71. The kit of Claim 70, wherein the two allele specific genotyping oligonucleotides are packaged in separate containers.

72. A kit for determining the identity of the nucleotide pair at the -511 position of the IL-1β gene (at position 1423 of sequence X04500) from the transcriptional start site for the two copies of the IL-1β gene present in the patient; comprising:

a) a container comprising at least one reagent specific for detecting the nature of the nucleotide pair at the at the -511 position of the IL-1β gene (at position 1423 of sequence X04500) from the transcriptional start site for the two copies of the IL-1β gene present in the patient; and

b) instructions for interpreting the results based on the nature of the said nucleotide pair.

73. A kit for determining the identity of the nucleotide pair at the polymorphic site at position -31 base pairs upstream (at position 1903 of sequence X04500) from the transcriptional start site; comprising:

a) a container comprising at least one reagent specific for detecting the nature of the nucleotide pairs at the polymorphic site at position -31 base pairs upstream (at position 1903 of sequence X04500) from the transcriptional start site; and

b) instructions for interpreting the results based on the nature of the said nucleotide pair.

74. The method of any one of Claims 10 to 12, wherein the determination step (a) further comprises the use of a kit of any one of claims 63, or 65 to 72.

75. The method of any one of Claims 13 to 15, wherein the determination step (a) further comprises the use of a kit of any one of claims 64 to 71, or 73.